TRANSATLANTIC ECONOMIC COUNCIL

ANNEX - REVIEW OF PROGRESS UNDER THE FRAMEWORK FOR ADVANCING TRANSATLANTIC ECONOMIC INTEGRATION
BETWEEN
THE UNITED STATES OF AMERICA
AND
THE EUROPEAN UNION

I. Regulatory Cooperation

A. Horizontal

General

The United States and the EU continue to work towards removing unnecessary differences in regulation by deepening collaboration, sharing best practices, and jointly extending expertise to support third-country regulatory efforts. The Office of Information and Regulatory Affairs (OIRA) in the U.S. Office of Management and Budget (OMB) and the Commission Based their work on a joint report from May 2008 on how both sides address trade and investment impacts in their respective regulations. The Commission Impact Assessment Board actively monitors this in its quality control of the Commission Impact Assessments. The EU followed with revised guidelines to ensure that such impacts are considered; in the United States, regulations that have international impacts are specially flagged.

Substantial progress has been achieved between U.S. and EU regulators in the High-Level Regulatory Cooperation Forum (HLRCF). The Forum met twice in 2009, during July and October. During its July 24 meeting, the Forum reviewed progress in the areas of impact assessment, the use of standards in regulation, risk assessment, and import safety. Energy efficiency standards were among the issues discussed during the July and October 26 meetings. The two sides agreed to develop an inventory of regulations and initiatives in this area. OIRA and DG Enterprise presented papers during the October 26 meeting describing the U.S. and EU approaches to the use of voluntary standards in support of regulation. Both sides also discussed the usefulness of continued dialogue regarding developments related to the risk analysis and regulation of nanomaterials.

These discussions in the HLRCF were reported to the October 27 TEC meeting. Contacts between OIRA and the U.S. Office of Science and Technology Policy (OSTP) with the Commission's Directorate of Health and Consumer Affairs (DG SANCO) to facilitate an international dialogue on risk analysis, led to risk analysis discussions starting in July 2008 that included representatives from the United States, EU, and Canada. In January 2009, OMB, SANCO, and Canadian government risk managers reinstituted the practice of weekly conference calls to ensure progress in work groups that will develop white papers in three focus areas: 1) development of a framework for exposure assessment; 2) uncertainty and terminology; and 3) new/rapid approaches to risk assessment. The risk assessment papers are expected to be available for broad discussion in 2010.

Standards Dialogue

Standards and conformity assessment can play a critical role in facilitating transatlantic trade

and have been a component of work conducted under the Framework since its inception. The principal objective of this work is to achieve more effective coordination on standards and conformity assessment issues in support of regulatory and public policy goals. The partners in the U.S.-European Commission Dialogue are the European Commission's Directorate for Enterprise and Industry and the U.S. Department of Commerce. A discussion paper/report on the use of standards in regulation was tabled at the October 2009 HLRCF. Both sides have agreed in October 2009 to consider priority areas for future work and to discuss further how to involve stakeholders more closely in the activities of the dialogue. The U.S. standards body, ANSI, and the European standardization organizations (CEN, CENELEC and ETSI) conduct their own dialogue. They meet regularly, together with representatives of relevant U.S. and EU government agencies, and through this provide input to the U.S.-European Commission Dialogue. The next dialogue between the European standardization organizations and ANSI, including U.S. and EU government representatives, is currently planned for 2010.

B. Sectoral

Regulatory Dialogue on Food Safety

The United States and the EU share a strong commitment to ensuring the safety of food consumed by their citizens. An official from the European Food Safety Authority (EFSA) joined the staff of the U.S. Food and Drug Administration (FDA) for a two-year period effective September 1, to further facilitate exchange of scientific information and regulatory cooperation. Based on more intense contacts between the U.S.-EU Animal Health Technical Working Group (AHTWG) and the U.S.-EU Plant Health Technical Working Group (PHTWG) at the technical level, an expert meeting is scheduled along with the Joint Management Committee (JMC) of the US-EU Veterinary Equivalency Agreement, for late 2009 or early 2010.

Pharmaceuticals

Communication between FDA, the European Commission and the European Medicines Agency (EMEA) increased significantly during the last year, due to greater maturity of activities in cluster areas, enhanced discussion on pandemic issues, and the launch of several pilot projects. This interaction has been facilitated by placement of a U.S. liaison staffer in EMEA in June 2009 and the planned placement of an EU liaison staffer in FDA in 2010.

Arrangements allowing the EMEA and the FDA to exchange confidential information as part of their regulatory processes relating to medicines were extended in September 2005 for five years. The September annual meeting between the Commission, EMEA, and the FDA confirmed our joint interest in prolonging confidentiality arrangements beyond 2010 and extending their scope to the exchange of safety-related information for non-centrally authorised medicines. The Commission, EMEA, and FDA discussed whether and how drug-medical device combination products should be taken into the international harmonization sphere. During the September meeting, we also discussed the important public health issue of antimicrobial resistance, including possible transatlantic cooperation on regulatory and scientific approaches to provide incentives to develop new antimicrobials for treatment of infections caused by multi-drug-resistant bacteria.

Finally, we made significant progress on implementation of the Transatlantic Administrative

Simplification Action Plan of June 17, 2008, in projects spanning 18 different areas, including inspections, biosimilars, scientific advice and counterfeiting.

Medical Devices

FDA and the DG Enterprise are engaged in both bilateral and multilateral discussions to harmonize regulation of medical devices. Based on a 2007 Memorandum of Confidentiality which permits the exchange of confidential information on regulated products between U.S and EU regulators, in September 2009, officials from the FDA and the European Commission discussed a process for recognition of inspection audits. This process will continue through talks with EU member states and the Notified Bodies. The FDA agreed to provide the Commission with draft guidance and documents on implantable medical devices, reprocessing medical devices, and cellular products. Both sides agreed to develop a joint workshop on genetic testing (in-vitro diagnostic testing devices) and to work on establishing a system for unique device identification and traceability requirements.

Cosmetics

Through the International Cooperation on Cosmetics Regulation (ICCR), the United States, the EU, Japan, and Canada have intensified efforts to validate 34 alternative tests to reduce testing of cosmetics on animals. In March 2009, the EU introduced a ban on testing of cosmetics ingredients on animals for all but three human health effects, but not all alternative tests are available. For the three remaining health effects, a ban will be introduced in March 2013. During its July 2009 meeting in Italy, the ICCR recommended that an ad hoc working group, composed of representatives from regulatory bodies and industry, be developed to discuss criteria and safety substantiation for nanomaterials in cosmetics.

Chemicals

Discussions on chemicals are more relevant than ever with important and recent developments on both sides of the Atlantic, e.g., the EU Registration, Evaluation, Authorization and restriction of Chemicals (REACH) program transitioning into its registration phase, announcements of principles for reform of the U.S. Toxic Substance Control Act (TSCA) and enhancements to chemicals management in the U.S. Bilateral efforts in this area through the existing regulatory cooperation dialogue between the U.S. Environmental Protection Agency (EPA) and its counterparts in the European Commission and the European Chemicals Agency (ECHA), have proved useful. The Dialogue aims to facilitate improved risk reduction by sharing experiences and expertise in the sound management of chemicals while promoting regulatory best practices and information sharing on scientific, technical and related challenges among other issues of mutual interest. It meets periodically, usually on the margins of existing meetings, and may include other government agencies depending upon agenda topics and mutual agreement.

While productive discussions have occurred in earlier meetings 2007-8, most recently, these have continued in different international fora such as the OECD, and on the margins of international chemicals events such as the second International Conference on International Chemicals Management (ICCM2) and the Fourth Conference of the Parties to the Stockholm Convention, both held in May 2009. Notably, transatlantic chemicals management issues have converged in pursuit of a legally-binding instrument on mercury, with a global partnership to eliminate lead in paint and other outreach and collaboration on perfluorinated

chemicals and nanomaterials, in addition to continued collaboration in these areas within the OECD.

Future discussion topics may include: development and implementation of respective regulatory regimes including recent developments in the United States on TSCA reform; EPA's existing chemicals management program; the use and application of computational tools; co-operation on assessment and risk management activities; emerging issues with manufactured nanomaterials; and the Globally Harmonized System of Classification and Labeling (GHS); among others.

Electrical Equipment

In October 2008, the U.S. Occupational Safety and Health Administration (OSHA) issued a Request for Information (RFI) from stakeholders on a proposal from the European Commission that OSHA permit the use of a Supplier's Declaration of Conformity (SDoC) as an alternative to the Nationally Recognized Testing Laboratories (NRTLs) product approval process. OSHA is reviewing and analyzing comments that were submitted before the January 20, 2009 RFI deadline and will announce the results as soon after the October 2009 TEC meeting as feasible.

Auto Safety

Over the past year, the EU and U.S., (along with the other contracting parties to the 1998 agreement, which include the PRC, India and Japan) have worked under the UN- ECE World Forum for the Harmonization of Vehicle Regulations (WP.29) to achieve new global technical regulations (GTRs) in the areas off-cycle emissions and pedestrian safety systems for highway vehicles. In addition, work continues on a longer term GTR for hydrogen-powered vehicles. Moreover, the National Highway Traffic Safety Administration - NHTSA - and DG Enterprise have confirmed new items for co-operation at WP.29 in other areas of motor vehicle safety. These include the development of GTRs for motorcycle safety and test devices for vehicle crash worthiness.

U.S.- EU Toy Safety Dialogue

Following the recommendation of the November 2007 TEC meeting, the U.S. Consumer Product Safety Commission (CPSC) and the European Commission's Directorates General for Enterprise (DG Enterprise) and Health and Consumers (DG SANCO) participate in a Toy Safety Working Group, set up in May 2008. The Working Group met three times by videoconference in 2009, and members maintained close contact between meetings. This working group functions as a focal point to discuss the safety of imported products. Over the past six months, the working group has discussed issues arising from our new legal frameworks, aiming to reach common approaches to problems when possible. Special attention has been paid to the format and content of product traceability labels and of declarations of conformity; new standards for magnetic toys; testing methods for phthalates and heavy elements in toys and children's books; and standardisation of various children's products (other than toys). The working group will continue to exchange information on implementation of the toy safety and other children's product safety legislation in the United States and the EU, and on our respective enforcement activities, and will explore possible convergence in specific areas. CPSC and DG SANCO are discussing a possible meeting in China in Spring 2010, to build upon the successful joint product safety outreach effort in

China in September 2008.

Internet Security for Consumers

The U.S. Federal Trade Commission (FTC) and DG SANCO are working on an agreement on cooperation in the enforcement of consumer protection laws. The Commission obtained a negotiating mandate from the Council in May 2009 and the first negotiations took place in June. Discussions on the draft text continued during videoconferences held in July and October. The aim is to come to an agreed text by the end of 2009, and to conclude the agreement during 2010.

II. Lighthouse Priority Projects

The United States and the EU have worked actively on the priority issues for transatlantic economic integration identified at the April 2007 Summit (the so-called "Lighthouse projects") and can report progress on a number of them.

A. Intellectual Property Rights (IPR)

The U.S.-EU IPR Working Group met most recently September 23-24, 2009. A copy of the final report of the September meeting can be found at www.stopfakes.gov. The public session of the meeting opened with a briefing for transatlantic stakeholders, hosted by the U.S. Chamber of Commerce's Global Intellectual Property Center. U.S. and EU officials reviewed the status of various cooperative efforts and ongoing multilateral discussions currently underway, pledging to keep the various constituency groups informed as negotiations progress. Government-to-government discussions focused on common goals in key third-country markets – e.g., China, Russia, and India, as well as Brazil, Canada, and ASEAN – and other areas of IPR cooperation. Both parties agreed to continue to work together to strengthen intellectual property protection through bilateral and multilateral mechanisms, and we reaffirmed our commitment to the successful completion of the Anti-Counterfeiting Trade Agreement (ACTA) negotiations. Cooperation between U.S. and EU customs authorities has been noteworthy, resulting in joint seizure operations at U.S. and EU ports, the joint-development of a brochure "Protecting Intellectual Property at Our Borders" to educate rights holders on working with customs officials in the U.S. and EU, and the development of joint Web-Toolkit Product Guidelines to enable rights holders to develop toolkits to assist customs authorities in both markets with authenticating suspect shipments.

The next meeting of the U.S.-EU IPR Working Group is tentatively scheduled to take place in Europe during the first quarter of 2010. While the agenda is yet to be agreed, third-country cooperation discussions will continue to figure prominently; additional countries and/or regions of concern may be identified together with industry. The United States and the EU also will continue to work cooperatively to advance common objectives in the ACTA negotiations, and within the OECD and the United Nations. Discussions will be held on future joint operations between the two customs agencies, and DG Enterprise and the U.S. Department of Commerce will continue to cooperate in the development of resources for SMEs in both markets and linking their respective online IPR web portals to each other. The U.S. and EU also note industry concerns on the nexus between climate change negotiations, mitigation technology and intellectual property protection.

B. Trade and Transport Security

Secure trade: Mutual recognition of EU-US trade partnership programs is a flagship project agreed by the TEC in November 2007. Both sides are committed to achieving it according to the agreed EU/US roadmap revised in November 2008. The next step is regional workshops that will take place in Europe in the coming weeks to share best practices and information on Member States AEO programs. Legal discussions on the appropriate formalization of mutual recognition are also currently underway. All validation and legal work, for the purpose of finalizing mutual recognition discussions, should take place as soon as possible in time for the upcoming meeting of the U.S.-EC JCCC in early 2010 so that mutual recognition discussions can be brought to conclusion at that meeting.

Customs cooperation: In 2008/2009 the EU sent customs officers to the U.S. National Targeting Center-Cargo as part of our ongoing commitment to enhance transatlantic security. Based on a Commission report setting out the outcomes and recommendations of this pilot program the U.S.-EC Joint Customs Cooperation Committee (JCCC) will examine the possibility of a second phase to this cooperation.

C. Financial Markets

Since its foundation in 2002, the U.S.-EU Financial Markets Regulatory Dialogue has offered a robust, efficient and flexible platform to mutually exchange information, identify potential regulatory conflicts and work out solutions, as demonstrated by a solid track record of joint successes. More than ever in the current context, the informal U.S.-EU Financial Markets Regulatory Dialogue remains the forum of choice to ensure that the implementation of the U.S. and EU roadmaps for regulatory reform and G20 commitments at the domestic level are compatible and as convergent as possible and anchored in the global financial system.

As their respective regulatory reform roadmaps continue to unfold, the members of the U.S.-EU regulatory dialogue will continue to hold regular exchanges of information at all levels and monitor closely regulatory developments on both sides of the Atlantic. The FMRD will next meet on October 27, 2009.

Detailed description of the progress achieved to date can be found in Annex 2.

D. Innovation and Technology

Innovation, technology development and deployment, and entrepreneurship are critical to promoting growth and job creation. In recognition of this, the Framework specified a number of areas for U.S. and EU collaboration to promote innovation. The TEC today agreed to take a number of steps to enhance this collaboration, including establishing a new Innovation Dialogue. The new Dialogue will be co-chaired by senior officials from the Department of Commerce, DG Enterprise. It will monitor and seek to accelerate progress on a wide range of collaborative innovation activities. Possible topics for discussion include in the areas of innovation policy, health information technology, information and communication technologies, and clean energy technologies products. In the period before the next TEC meeting, the United States government and the European Commission will conduct joint stakeholder outreach, complete the assessment of priority projects, and agree on a work program for the Innovation Dialogue.

In other areas, the United States and the EU made strides in 2009 in our cooperation on e-accessibility standards, RFID, and e-health.

-- Our discussions on e-accessibility continue to proceed well. The European Commission will soon focus on Phase II of the mandate (M376) to European Standards Organisations to develop a European Standard (EN) on functional accessibility requirements for the public procurement of information and communication technology products and services. U.S. participation in the European work will help foster harmonization with the revised U.S. standards. The U.S. revision of the accessibility standards of section 508 of the Rehabilitation Act and Section 255 of the Telecommunications Act will soon be circulated for public comment. The EU participated in preparation of these texts, and European stakeholders are invited to actively contribute comments. Next steps in the dialogue are expected to be taken at the beginning of next year, when both activities will be operational.

-- On RFID, the Commission issued a recommendation in May 2009 on the implementation of privacy and data protection principles in RFID-supported applications, which took into account U.S. government input. In addition, the United States and the EU held a networking day on U.S.-EU RFID pilot projects as well as the Second Transatlantic Symposium on the Societal Benefits of RFID in May.

-- On e-health, the United States and the EU are engaged in dialogue aimed at promoting improved health and care through the effective use of interoperable health information technology and the secure exchange of electronic health information.

E. Investment

The European Commission and the U.S. government continue to engage in the Investment Dialogue, focusing on issues that could impact the bilateral EU-U.S. investment relationship, key third countries, and global investment issues. During 2009, the Investment Dialogue continued formal and informal discussions. Looking forward, both sides remain committed to preserving and promoting open investment policies, implemented in a non-discriminatory manner, on both a bilateral and a global basis. Plans are underway for future Dialogue engagements to continue reducing barriers to international investment.